## **REMARKS**

- Claims 1-4, 8, 10, 12-14, and 16-23 are pending.
- Claims 1-4, 10, 12, and 18-20 are rejected.
- Claims 8, 13, 14, 16, 17, and 21-23 are withdrawn from consideration.

Applicants wish to point out that the above statement of claim status does not match the disposition of Claims that the Examiner listed in the current Office Action.

Applicants believe that the above is a correct statement of the current status of the claims. Please clarify. Applicants request clarification from the Examiner.

Applicants have not amended the claims in this response.

## **Drawings**

35 CFR § 1.81 requires a drawing when necessary for the understanding of the invention. See, for example, 37 CFR § 1.81(a). The language that the Examiner uses "admits of illustration by a drawing to facilitate the understanding of the invention" comes from the optional language of § 1.81(b), which describes what a drawing may contain not whether or not a drawing is required. Applicants believe that a drawing is not necessary for understanding the current invention. The Examiner must agree with this because the Examiner was able to issue two previous Office Actions without a drawing and therefore must have understood the invention without a drawing.

The Examiner has rejected claims 1-4, 10, 12, 18, and 19 under 35 USC-§ 103(a) as being unpatentable over Fearnot et al., US patent number 5,609,629. According to the Examiner, Fearnot teaches a stent with a coating containing anti-thrombotic and anti-inflammatory agents. The Examiner recognizes that Fearnot does not teach a "device comprising a coating including a first region having a component for reducing or preventing the formation of thrombi and a second region having a component for

reducing or preventing infiltration of macrophages in the thrombi, wherein the second region of the coating is positioned beneath the first region" as specified in claim 1.

The Examiner says that at the time the invention was made positioning the anti-inflammatory-agent region beneath the anti-thrombotic-agent region would have been an obvious matter of design choice. For this arrangement of regions to be an obvious matter of design choice, one of ordinary skill in the art would have had to recognize the equivalence between structures with region one over region two and structures with region two over region one. Presently, the Examiner has presented no evidence of that equivalence, nor has the Examiner argued why one of ordinary skill in the art would expect that equivalence. Until the Examiner rectifies this omission, a prima facie case of obviousness has not been made out. Furthermore, the contact surface between the device and bodily fluids will be of a different nature. The Examiner is requested to explain this. The surface in contact with bodily fluid would be expected to have predominately anti-thrombic characteristics in the claimed invention. Why would one of ordinary skill in the art expect that structure to function similarly to the reverse configuration which would be expected to have predominately anti-filtrative properties?

The Examiner then goes on to state that "one of ordinary skill in the art would have expected Applicant's invention to perform equally well with the first coating in the first region position[ed] beneath the second region because the bioactive materials in the first and second regions would prevent inflammatory and thrombi". Since the Examiner has provided no evidence that one of ordinary skill in the art at the time the invention was made would have so expected, Applicants presume that the Examiner is taking official notice of facts outside the record. Applicants traverse this assertion and request that the Examiner cite a reference demonstrating those facts, as required by MPEP § 2144.03. Alternatively, Applicants request the Examiner to provide an affidavit stating those facts.

Since a prima facie case of obviousness has not been made out, Applicants request the Examiner to remove this obviousness-based rejection.

The Examiner has rejected claim 20 under 35 USC § 103(a) as being unpatentable over Fearnot in view of Kunz.

Claim 20 depends from claim 19. As discussed above, the Examiner has not made out a prima facie case of obviousness for claim 19. Therefore, claim 20 is patentable regardless of the propriety of the rejection set out in section five of the instant Office Action. The cited combination fails to teach the arrangement of region one over region two.

Since the cited combination fails to teach each and every element of claim 20, please remove this rejection of claim 20.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,

Date:

30 April 2003

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Charles E. Runyan Attorney for Applicants Reg. No. 43,066 Claim 20 depends from claim 19. As discussed above, the Examiner has not made out a prima facie case of obviousness for claim 19. Therefore, claim 20 is patentable regardless of the propriety of the rejection set out in section five of the instant Office Action. The cited combination fails to teach the arrangement of region one over region two.

Since the cited combination fails to teach each and every element of claim 20, please remove this rejection of claim 20.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

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